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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,724	05/23/2000	Vladka Curin-Serbec	201196/50 (80242/US)	3140

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/576,724	Applicant(s) CURIN-SERBEC, VLADKA	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 18, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10,12-15,17,18 and 20-31* is/are pending in the application.

4a) Of the above claim(s) *10,15,17,18 and 21-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12-14 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the groups are so closely related that they require common areas of consideration, therefore it would not be a burden to search. This is not found persuasive because, the state of the art is such that it recognizes the differences in these groups. Because the fields of search must be pertinent to the subject matter covered by the claims, the search for one group will not be coextensive for the other group resulting in a serious burden to the examiner to evaluate all groups.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

> To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 9, is attached to the instant Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what applicant intends with the limitation "three dimensional structure". Is "three dimensional structure" referring to a non-denatured prion particle? Or is the "three dimensional structure" referring to a proteinase K resistant prion particles? The claim is not clear whether the samples may not be treated with proteinase K or any other denaturant. Clarification of what is intended with the "three dimensional structure" is required.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what applicant intends with the limitation "linked to a marker". Does this mean that the antibody itself has to be biotinlyated or attached to an alkaline phosphatase marker. Or can a secondary antibody link the marker to the claimed monoclonal antibody and thereby meet the limitation of "linked to a marker"? Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent the specific hybridoma cell line CNCM- I-2476 is required to practice the claimed invention. As such it must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by an enabling deposit of the hybridoma. It is noted that the Applicants have deposited the hybridoma but there is no indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claims 1-5, 12, 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed monoclonal antibody produced by the hybridoma CNCM- I-2476, does not reasonably provide enablement for other antibodies that are able to bind the prion specific protein structure while not binding the normal form of the prion protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The antibodies of the invention are produced by linking by peptides to a carrier molecule, in this case KLH and injecting this mixture into an animal. Fishleigh et al. (U.S. Pat. No. 5,773,572) disclose antibodies that are made via the same methods as the antibody of the instant invention, using peptides comprising the sequences of SEQ ID 1 and 2 (Fishleigh et al. SEQ ID NO: 37 and 48; see columns 19-21 and table III [especially VIIIb = SEQ ID 48 peptide]). The antibodies of Fishleigh et al. all are able to bind the normal prion protein and do not specifically bind the diseased form. It is clear that making antibodies that only recognize the

diseased form is not a trivial enterprise which can be achieved using specific repeatable method. Therefore, applicant is enabled only for the single disclosed antibody made from the CNCM- I-2476 hybridoma.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5, 13 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Rourke (U.S. Pat. No. 6,261,790 B1).

The instant invention is drawn to an antibody that selectively binds to a "three dimensional conformation" of the C-terminal part of PrP-Sc while not binding PrP-C. The specification on page 6, lines 16-25, indicates that the conformational particularity required for the antibody is retained utilizing SEQ 1 or SEQ ID2 which differ solely by a Glu/Gln at amino acid #6 in the sequence. Claim 3 specifically refers to an antibody directed to SEQ ID NO: 1. The limitation that the C-terminal region for the structure minimally comprises amino acids 190-214, does not exclude the whole prion protein structure. The antibody may be a polyclonal, monoclonal or fragment thereof. The antibody is produced from a hybridoma cell line.

O'Rourke discloses an antibody that specifically binds the three dimensional structure of PrP-Sc (see claim 1 and SEQ IDNO:3). This antibody is made directed to a peptide (SEQ ID NO:2 of the instant invention) which, according to the specification, retains the requisite "three dimensional structure" required of the antibody and thereby it is expected that the antibody to SEQ ID NO:2 would also bind SEQ ID NO:1 of the instant invention. The antibodies are used for immunohistochemical analysis and they are visualized by "linking" a secondary antibody which contains the visual marker to the disclosed monoclonal antibody. The reference also discloses a hybridoma cell line (see claims 1-4) for the production of the monoclonal antibody. Therefore, the instant invention is anticipated by O'Rourke et al.

Claims 1, 2, 4, 5, 12, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Prusiner et al. (U.S. Pat. No. 5,846,533).

The instant invention is drawn to an antibody that selectively binds to a "three dimensional conformation" of the C-terminal part of PrP-Sc while not binding PrP-C. The specification on page 6, lines 16-25, indicates that the conformational particularity required for the antibody is retained utilizing SEQ 1 or SEQ ID2 which differ solely by a Glu/Gln at amino acid #6 in the sequence. The limitation that the C-terminal region for the structure minimally comprises amino acids 190-214, does not exclude the whole prion protein structure. The antibody may be a polyclonal, monoclonal or fragment thereof. The antibody is produced from a hybridoma cell line.

Prusiner et al. discloses antibodies that are able to bind native PrP-sc *in situ* (see claim 1 and example 17). The reference discloses antibodies D14, D7, D18, R2, D4, R1 and D10 (see

figure 9) that bind to the native PrP-Sc while not binding to the normal PrP-C protein (see summary of invention, and figures 11 and 12). In addition, the antibodies can be used to treat an animal (column 21, lines 17-42). Therefore, the instant invention is anticipated by Prusiner et al.

Allowable subject matter

Claims limited to the specific monoclonal antibody derived from the CNCM- I-2476 hybridoma cell line would be allowable.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER